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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,506	12/21/2001	John D. DeNuzzio	P-4899	2199

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3736

13

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,506

Applicant(s)

DENUZZIO ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-69 is/are allowed.
- 6) ☒ Claim(s) 1-19, 22-40 and 43-65 is/are rejected.
- 7) ☒ Claim(s) 20, 21, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the auxiliary electrode that is adapted to pass into the stratum corneum while contacting the surface skin must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 31, 48, 54, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, with respect to claims 7, 31 and 54, applicant has stated that the auxiliary electrode can extend into the stratum corneum while contacting the surface of the skin. Applicant has not shown this feature in the drawings and it is unclear exactly how an electrode lies on the surface of the skin and extends through the surface simultaneously. With respect to claims 48 and 64, applicant has amended the specification to recite that the potential may be adjusted. However, it follows a paragraph that specifically states that there is no reason to adjust the potential, as any

error is negligible, Again, this appears to be contradictory and it is unclear to what end the potential is adjusted or how it is done. No art is being applied to claims 48 and 64, but upon resolution of this issue, the art rejection will be revisited. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pao. Pao shows in figure 6 a device having the same structure as the claim, i.e. and outer conductor (auxiliary electrode) adapted to contact the skin and surrounding an inner electrode (active electrode) which extends outward from the auxiliary electrode by 0.2-0.88 mm (see bottom of column 6), which is in the range listed by applicant. Pao is designed for a different use. However, the nature of use of a device is not sufficient to define over a device of identical structure. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) Applicant might define over this reference by reciting that the electrodes are connected to a device for determining analyte concentration, or use similar language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 9-19, 22-26, 33-40, 43-47, 49, 56-63, and 65 are rejected under 35 U.S.C. 103(a) as being obvious over Gross et al 6,275,717 in view of Sohrab. Gross et al shows a device for measuring at least one analyte in a patient, including an active electrode 15 that electrochemically detects glucose in the blood, and an auxiliary electrode 16 or 17, that partially surrounds the active electrode. The length of the active electrode in Gross is longer than the length specified by applicant's claims. However, Sohrab teaches that having a glucose sensing needle extend into the blood unnecessarily causes patient pain and that having the needle only access interstitial fluid provides the same results without hurting the patient (see column 1). The length of the needle in Sohrab is 1000-2000 micrometers. Therefore, it would have been obvious to modify Gross et al to have the length of the needle by 1000-2000 micrometers, so as to avoid hurting the patient. Claim 2 is rejected because Gross shows a base 13 integral with auxiliary electrode, where the active electrode extendable beyond the base to a sufficient depth to access the glucose (see figures 12 and 13). Claim 9 is rejected in that there is a communication device 23 for communicating with an external device. Claim 10 is rejected in that a patient may wear the device of Gross et al. Claim 11 is rejected in that Gross detects hydrogen peroxide, which is an electrolyte. Claim 12 is rejected in that Sohrab teaches that having one or a plurality of active electrodes for making measurements are equivalent designs. Hence, it would have been obvious to provide Gross et al with a plurality of electrodes, as it is merely the substitution of one known equivalent design for another. Claim 13 is rejected in that

Art Unit: 3736

the electrodes 16 or 17 "substantially" surround the active electrode, being as applicant has not provided a definition of the word "substantially." Claim 14 is rejected in that the auxiliary electrode is coupled to the base portion, near where the active electrode extends. Claim 15 is rejected in that an electrical potential is applied to the active electrode (see column 11, lines 35-46). Claim 16 is rejected in that the analyte is electrochemically active. Claim 17 is rejected in that one of the substances measured in detecting glucose is oxygen. Claim 18 is rejected in that the active electrode is platinum-iridium (see column 9, line 58). Claim 19 is rejected in that one of the electrodes 16 and 17 is an auxiliary electrode and one is a reference electrode. Both electrodes are equally spaced from active electrode 15. Claims 22 and 23 is rejected in that there is a delivery device integral with the assembly that is adapted to deliver insulin based on the glucose reading. (see 7, lines 52-57). Claim 24 is rejected in that, in addition to the features discussed above, electrode 15 is impregnated with glucose oxidase (see column 10, lines 25-31). Claims 25, 26, 33-40, 43, and 44 are rejected for the reasons given above. Claim 45 is rejected in that Gross et al further teaches the method of placing the electrode against a patient's skin, where the device has an active electrode 15 and an auxiliary electrode 16 or 17, the auxiliary electrode contacting the patient's skin when the active electrode is in the body, applying a potential to the electrodes, and measuring the current from the electrochemical reaction to measure glucose. Claim 46 is rejected in that the current is an integrated current (see column 12, line 20). Claims 48, 49, 56, 57, 59-63, and 65 are rejected for the reasons given above.

Claims 3-5, 27-29, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Sohrab, as applied to claims 1, 2, 9-19, 22-26, 33-40, 43-47, 49, 56-63, and 65 above, further in view of Kanner et al. The needle of Gross is not retractable. The examiner notes that Kanner teaches a lancet where the body piercing member is retracted after use automatically via a spring so as to prevent cross contamination and unintentional pricking of the patient. From this teaching, it would have been obvious to modify the above combination to have the needle extend for use and then retract back inside the device, to limit the device to a single use and prevent cross contamination and injury. The examiner notes that making the retraction and extension automatic or manual does appear to be for a specific purpose and it does not solve a stated problem. Accordingly, it would have been a mere matter of design choice to make the extension and retraction automatic or manual.

Claims 6, 30, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view in view of Sohrab, as applied to claims 1, 2, 9-19, 22-26, 33-40, 43-47, 49, 56-63, and 65 above, further of Becker et al. Gross et al does not have an abraded surface on the auxiliary electrode. Becker et al teaches that such a surface is required to decrease the skin resistance and increase measurement accuracy. Hence, it would have been obvious to modify the above combination to use such an abraded surface, to increase measurement accuracy.

Claims 8, 32, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of in view of Sohrab, as applied to claims 1, 2, 9-19, 22-26, 33-40, 43-47, 49, 56-63, and 65 above, further Causey III, et al. Gross et al does not have

data storage for storing the glucose levels. Causey III et al provides such storage on a similar device so that the physician can review the trends in the patient's condition at a later time. Therefore, it would have been obvious to modify the above combination to use such data storage, to allow improved care by the physician.

Claims 66-69 are allowable.

Claims 20, 21, 41, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20, 21, 41, 42, and 66-69 define over the art in that none of the art shows a plurality of active electrodes on a single device, for sequential use, as claimed. The examiner notes that a plurality of devices like that of Gross might be provided, and they would be adapted to sequential use, but that is a plurality of devices, not a device as claimed.

Claims 7, 31, and 54 would be allowable if the rejection under 35 USC 112, first paragraph rejection were overcome in that define over the art in that none of the art shows the auxiliary electrode that contacts the surface of the skin and extends into the stratum corneum while the active electrode extends through the stratum corneum, as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Blubaugh teaches in column 3, lines 39-56, that it is necessary in a 3 electrode measuring system to adjust the voltage.

Applicant's arguments filed 11/25/2003 have been fully considered but they are not persuasive.

Most of applicant's arguments are deemed moot in view of the new grounds of rejection.

However, with respect to the Kanner reference, applicant has asserted that Kanner, which is a lancet, does not provide motivation to modify Gross which is an electrode sensing device, to make the needle retractable. However, it is the examiner's opinion that Kanner teaches what has become well known in the art, when using medical needles, that contact blood, the must be protected from contacting other people, such as the medical staff, to avoid the spread of disease. Hence, it is the examiner's position that the combination is motivated.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

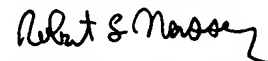
Art Unit: 3736

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
February 21, 2004

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